REMARKS

This document is submitted in response to the final Office Action dated February 5, 2007 ("Office Action").

Claims 6-17, 20, and 22-33 are currently pending. Among them, claims 22-25 are allowed and claims 16, 17, and 20 withdrawn.

Applicants have cancelled claims 6-15 and 33. The cancellation of claims 6 and 7 has necessitated rewriting claims 26-28 in independent forms and changing dependency of claims 29-32. In addition, Applicants have added new claims 34 and 35, support for which can be found, in, e.g., original claims 7, 28, and 29. No new matter has been introduced.

The amendment should be entered as it raises no new issues that will require further consideration or search and also does not touch the merits of the application within the meaning of 37 C.F.R. § 1.116(b).

Upon entry of the present amendments, claims 26-32, 34, and 35 will be under examination.

Allowable Subject Matter

Applicants thank the Examiner for recognizing that claims 22-25 cover allowable subject matter, i.e., a transformed cell/plant that contains a nucleic acid encoding SEQ ID NO:9, and methods of preparing same.

Rejections under 35 U.S.C. § 102

Claims 6-9 and 30-33 were rejected as being anticipated by Lin et al. See the Office Action, pages 8-9.

Applicants have cancelled claims 6-9 and 33, and have changed dependency of claims 30-32, all of which originally depend from rejected claim 6. Upon amendment, claims 30-32 now depend from claim 26, a claim not deemed anticipated by Lin et al. Applicants thus submit that these amendments have rendered this rejection moot.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 6-15 and 30-33 as obvious over Lin et al. in view of Maniatis et al. See the Office Action, page 9.

Applicants have cancelled claims 6-15 and 33, and have changed dependency of claims 30-32. For the same reasons set forth above, Applicant submit that the amendments have also rendered this rejection moot.

Rejections under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner rejected claims 6-15 and 26-33 for failing to satisfy the written description requirement. As Applicants have cancelled claims 6-15 and 33, only claims 26-32 are at issue.

Claim 26 is discussed first. This claim covers a transformed plant cell containing a DNA sequence that encodes a polypeptide that (1) is at least 70% identical to SEQ ID NO:9; and (2) has the activity of increasing sensitivity of a plant to an environmental factor. In other words, this claim encompasses a genus of polypeptides that meet the above two criteria.

As correctly pointed out by the Examiner, the Federal Circuit Court held in *University of California v. Eli Lilly* that "[a] description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of **structural features common to members of the genus**, which features constitute a substantial portion of the genus." 43 USPQ2d 1398, 1406 (Fed. Cir., 1997); emphasis added. The above-quoted law governs the written description requirement regarding biomolecules, e.g., DNA and polypeptide.

In this case, the specification discloses as many as 11 amino acid sequences of *Arabidopsis* TUBBY-like proteins (AtTLPs), i.e., SEQ ID NOs:1-11. All of these proteins regulate the response of *Arabidopsis* to environmental factors. See page 1, lines 19-23. It further teaches domains conserved among members of the AtTLP family, i.e., tubby domain, F-box, TUB1 and TUB2 motifs. See the specification at page 17, lines 16-31, and page 18, lines 1-11. Given the well-known structure-function

correlation, a skilled person would readily know that these conserved domains are critical to the protein activity, i.e., regulating plant responses to an environmental factor.

Further, Applicants would like to point out that some of the AtTLP members disclosed in the specification share less than 70% sequence identity to SEQ ID NO:9 and still possess the asserted activity as required by claim 26. To elaborate on this point, Applicants submit herewith a declaration of Dr, Shaw ("Declaration"), an inventor named in this application. According to Dr. Shaw's Declaration, at least five AtTLP members, i.e., AtTLPs1-3, 10, and 11, each has around 60-80% sequence identity to SEQ ID NO:9 and share the same activity of SEQ ID NO:9, i.e., binding specifically to *Arabidopsis* SKP1-LIKE 1 (ASK1) protein and regulating the sensitivity of seeds to exogenous phythormone abscisic acid (ABA), an environmental factor. See the Declaration, section 3. Taken together, the specification discloses polypeptides having as low as 60% sequence identity to SEQ ID NO:9 and sharing the same activity of SEQ ID NO:9. Note that all these functional polypeptides contain the conserved domains noted above. In view of these teachings, a skilled person in the art would know that a polypeptide having (i) as low as 60% sequence identity to SEQ ID NO:9 and (ii) the conserved domains would possess the asserted activity, let along a polypeptide at least 70% identical to SEQ ID NO:9 as recited in claim 26.

In view of the above remarks, Applicants submit that a skilled artisan would be fully aware that the conserved domains mentioned above, adequately described in the specification, are **structural features common to members of the genus** defined in claim 26. Following the holding of *University of California* quoted above, claim 26 satisfies the written description requirement. As the Examiner rejects claims 28-32 on the same ground, for the same reasons set forth above, Applicants submit that these claims also satisfy the written description requirement.

The Examiner does not dispute the fact that the present specification discloses functional domains common to members of the genus defined in claim 26. However, he contends that the specification fails to describe functional elements located in non-conserved domains of SEQ ID NO:9, variations in which would also affect the asserted

activity. See the Office Action, page 7, third paragraph. Applicants respectfully traverse below.

As pointed out above, the specification discloses as many as 11 amino acid sequences of AtTLPs. Some of them, e.g., AtTLP2, share as low as 60% sequence identity to SEQ ID NO:9 and retain the asserted activity. Based on this information, a skilled person would readily acknowledge that the non-conserved domains within SEQ ID NO:9 can vary without affecting its activity. In other words, he or she would know that these non-conserved domains do not include structures common to the members of the genus. Applicants thus submit that it is unnecessary, also impossible, to describe the non-conserved regions of each and every species of the genus defined in claim 26.

Applicants now turn to claim 27. This claim covers a transformed plant cell comprising a DNA that under a high stringency condition, hybridizes to a probe containing SEQ ID NO:20 or its complement and encodes a polypeptide that has activity of increasing sensitivity of a plant to an environmental factor.

Applicants would like to bring to the Examiner's attention that claim 27 is analogous to the "hybridization" claim presented in Example 9 of the Revised Interim Written Description Guidelines published by the Office on January 5, 2001 ("Guideline"). More specifically, the claim presented in Example 9 is directed to a genus of nucleic acids that hybridizes under highly stringent conditions to a complement of SEQ ID NO:1 and encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity. This example provides several nucleic acids that hybridize to SEQ ID NO:1 and proteins encoded thereby show the asserted function.

The analysis in Example 9 states:

> There is a single species disclosed (a molecule consisting of SEQ ID NO:1) that is within the scope of the claimed genus. There is actual reduction to practice of the disclosed species. Now turning to the genus analysis, a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination

with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention. See the Guideline, pages 36-37.

Like the claim presented in Example 9, claim 27 also encompasses a nucleic acid genus that hybridizes, under a high stringency condition, to a defined sequence, i.e., SEQ ID NO:20 or its complement. The present specification, like the specification of Example 9, also discloses a species that has been reduced to practice, i.e., SEQ ID NO:20. In addition, the specification discloses several other species, e.g., SEQ ID NOs:14 and 22, which, given their high homologies to SEQ ID NO:20, would hybridize to the complement of SEQ ID NO:20. The polypeptides encoded by SEQ ID NOs:14 and 22 possess the activity recited in claim 27, i.e., increasing sensitivity of a plant to an environmental factor. Following the analysis in Example 9, Applicants submit that "a representative number of species is disclosed [in the present specification] since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention [the nucleic acid genus encompassed by claim 27]." In other words, like the claim presented in Example 9, claim 27 also meets the written description requirement.

In view of the above remarks, Applicants respectfully request that the Examiner withdraw this rejection.

Rejection under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 6-15 and 26-33 were rejected for lack of enablement. See the Office Action, pages 2-5. As Applicants have cancelled claims 6-15 and 33, only claims 26-32 are at issue. Among them, the Examiner asserted one ground for rejecting claims 26 and 28-32 and a second ground for rejecting claim 27. Applicants traverse both grounds separately below.

I

Referring to claim 26, the Examiner asserts that the present specification fails to provide guidance on which region or regions of SEQ ID NO:9 recited in this claim are tolerable to mutations. More specifically, while acknowledging that the specification

discloses conserved domains of SEQ ID NO:9, the Examiner contends that mutations outside the conserved domains can also lead to protein inactivation. See the Office Action, page 3, second paragraph. Applicants respectfully disagree.

Claim 26, discussed above, encompasses a genus of polypeptides that are at least 70% identical to SEQ ID NO:9 (a member of the AtTLP family) and have the activity of increasing sensitivity of plant to an environmental factor.

As pointed out in Dr. Shaw's Declaration, other AtTLP family members, i.e., AtTLPs 1-3, 10, and 11, have amino acid sequences around 60-80% identical to SEQ ID NO:9 and possess the same activity of SEQ ID NO:9. See Section 3. As all of these proteins are members of the AtTLP family, they all contain the conserved domains noted above. It follows that their amino acid sequence variations reside in non-conserved domains. Since they all exhibit the asserted activity, a skilled artisan would readily acknowledge that variations within non-conserved regions would not affect the activity. In other words, he or she would know that non-conserved regions within SEQ ID NO:9 are tolerable to mutations.

Even if some SEQ ID NO:9 variants, i.e., at least 70% identical to SEQ ID NO:9, do not possess the asserted activity, this fact would not render claim 26 unpatentable for lack of enablement. Indeed, it is not legally required to show bioactivity of each SEQ ID NO:9 variant that falls in the scope of "at least 70% identical to SEQ ID NO:9 and has the activity of increasing sensitivity of a plant to an environmental factor." The law does not impose such a formidable burden on inventors seeking patent protection. In *In re Angstadt*, 190 USPQ 214, 218 (CCPA 1976), the court states that "Appellants (here, Applicants) are **not** required to disclose every species encompassed by their claims even in an unpredictable art" (emphasis original). Such a holding is only reasonable, since it is very difficult, if not impossible, to test and disclose all operative species in the chemical and biotechnology fields. Following *Angstadt*, it is also not necessary that Applicants disclose all functional SEQ ID NO:9 variants covered by claim 26 to satisfy the enablement requirement.

Of note, the specification teaches how to determine whether a polypeptide at least 70% identical to SEQ ID NO:9 has the activity of increasing sensitivity of a plant to an environmental factor. See page 30, lines 1-27. Following the teachings in the specification, a skilled person could easily make a SEQ ID NO:9 variant that falls in the genus defined in claim 26, i.e., introducing mutations into the non-conversed regions of SEQ ID NO:9 and then determining whether the resultant variants possess the asserted activity.

In view of the above remarks, Applicants respectfully submit that claim 26 is enabled. Claims 28-32 are rejected on the same ground. For the same reasons set forth above, it is believed that these claims also satisfy the enablement requirement.

II

Turning to the second ground for rejection, claim 27 covers a transformed plant including a nucleic acid that hybridizes to SEQ ID NO:20 or its complement under a high stringency condition and encodes a polypeptide that has activity of increasing sensitivity of a plant to an environmental factor.

The Examiner contends that the specification is not enabling for claim 27 in its entire scope as it encompasses nucleic acid sequences unrelated to SEQ ID NO:20, which can hybridize to SEQ ID NO:20 under the high stringency condition required by this claim. See the Office Action, page 4, third paragraph.0

Applicants pointed out in their response dated December 4, 2006, that the Examiner had overlooked the functional limitation recited in claim 27, i.e., "wherein the DNA sequence encodes a polypeptide that has activity of increasing sensitivity of a plant to an environmental factor." MPEP § 2173.05 states "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." Accordingly, to determine the scope of claim 27, the functional limitation recited therein must be taken into consideration. This limitation actually excludes any sequences that hybridize under a high stringency condition to SEQ ID NO:20 or its complement but **do not** encode proteins having the asserted activity. In other words, sequences unrelated

to SEQ ID NO:20, i.e., encoding proteins that do not possess the asserted activity, are not encompassed by claim 27.

Clearly, the Examiner has failed to consider the functional limitation recited in claim 27 when determining the scope of this claim. This approach is inconsistent with the law as re-stated in MPEP § 2173.05 and quoted above. Applicants thus submit that the Examiner's ground for rejecting claim 27 for lack of enablement is legally fallacious. Withdrawal of this rejection is respectfully requested.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The Petition for Extension of Time fee in the amount of $ 450 is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account

authorization. Please apply any other charges or credits to Deposit Account No. 50-4189, referencing Attorney Docket No. 70002-099001.

Respectfully submitted,

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